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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------------|-----------------------------|
| 10/550,734 | 09/26/2005 | Brian Nielsen | 2003015-US | 8354 |
| 69289 7590 07/23/2009 COLOPLAST A/S Attention: Corporate Patents Holtedam 1 DK-3050 Humleback, DENMARK | | | | |
| | | | EXAMINER JACKSON, BRANDON LEE | |
| | | | ART UNIT 3772 | PAPER NUMBER |
| | | | NOTIFICATION DATE 07/23/2009 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@coloplast.com
dkbvd@coloplast.com

Office Action Summary

Application No.

10/550,734

Applicant(s)

NIELSEN ET AL.

Examiner

BRANDON JACKSON

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to amendments/arguments filed 3/30/2009. Currently, claims 11-24 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 3/30/2009 have been fully considered but they are not persuasive. Applicant argues that Bray does not teach the disclosed density range of the Applicant's claimed invention. Further, Applicant argues the large density range disclosed in the Applicant's specification is irrelevant with respect to the obviousness, because it is merely another embodiment. However, the large range is not irrelevant. By Applicant disclosing such a large density range of 5-200 g/m²; Applicant is demonstrating a lack of criticality in a particular number or range. If Applicant's are allowed to disclose large ranges and then merely chose very small ranges in order to overcome prior art, then a dangerous precedent would be set, because Applicant would have an almost infinite amount of ranges to chose from for the sole purpose of overcoming prior art, even though their claimed invention may not actually be novel with respect to the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14, 16-18, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bray et al. (UK Patent Application Publication 2,377,177). Bray discloses a wound dressing (pg. 1, lines 1-2) comprising a web of gel forming fibers (pg. 1, lines 4-5) attached to a non-absorbent, reinforcing layer (pg. 3, lines 51-4), wherein the density of the web is in a range of 25-200 grams per square meter, which has a portion that falls within Applicant's range of 5-60 grams per square meter. The gel-forming fibers comprise alginate (pg. 1, lines 6-7). The reinforced layer and the web are attached by needling (pg. 3, lines 6-7) or thermal bonding (pg. 3, lines 9-10). The reinforced layer obviously could be woven, similar to other layers of the dressing (pg. 1, lines 17-19). The dressing comprises an active agent that is an anti-bacterial agent (pg. 1, lines 23-24). The dressing comprises silver calcium alginate or silver calcium alginate (pg. 1, lines 12-14). Bray fails to explicitly state the reinforcing layer density less than 50 g/m², preferably between 20 and 30 g/m². Moreover, Applicant's specification states the density range of the reinforcing layer can be from 5 to 200 g/m²; which is a large range. Therefore, the Bray device would function the same as

Applicant's claimed invention and the optimum density range can be determined via testing of the device. It would be obvious to one of ordinary skill in the art at the time of the invention to have the fabric layer density to be 5 – 60 g/m² and the reinforcing layer to have a density range of 20-30 g/m²; since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Obviously, combined densities in these ranges could add up to 50 g/m².

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bray et al. (UK Patent Application Publication 2,377,177) in view of Sessions et al. (US Patent 6,346,653). Bray substantially discloses the claimed invention; see rejection to claim 11 above. Bray fails to disclose an adhesive means for attaching the web to the reinforcing layer. However, Sessions discloses a wound dressing (10) comprising an adhesive means (28) for attaching a first layer (30) to a second layer (32). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to substitute Bray bonding means for the adhesive means, as taught by Sessions, because the adhesive is a well known means in the art for securing layers of a wound dressing.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bray et al. (UK Patent Application Publication 2,377,177) in view of Nielsen (US Patent 6,998,509). Bray substantially discloses the claimed invention, specifically including an active ingredient within the dressing; see rejections to claims 11 and 17 above. Bray

fails to disclose a pain-relieving agent incorporated in the dressing. However, Nielsen teaches a wound care device comprising a pain-relieving agent (col. 9, lines 27-31). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the active ingredient in the dressing of Bray to substitute a pain relieving agent for the active ingredient, as taught by Nielsen, in order to provide the user with the comfort of not feeling the pain from the wound under the dressing. Such a modification would have been obvious on one of ordinary skill in the art at the time of the invention was made to substitute the pain relieving agent for the antibacterial agent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772